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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,805	08/03/2001	Seiichi Shibamura	P21313	7834
7055	7590	02/22/2005	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			HOLLERAN, ANNE L	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,805

Applicant(s)

SHIBAMURA ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11, 12, 14-21 and 23-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 12, and 26-29 is/are allowed.
- 6) ☒ Claim(s) 11, 14-21, 23-25 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed Jan. 2, 2004 is acknowledged. Claims 8-10, 13, 22 were canceled.

Claims 25-36 were added

2. Claims 1-7, 11, 12, 14-21 and 23-36 are pending and examined on the merits.

Claim Rejections Withdrawn:

3. The rejection of claims 1-7, 12, 14-21 and 24-36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

4. The rejection of claims 1-7, 12, 14-21 and 24-36 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims.

Claim Rejections Maintained:

5. The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons of record. The amendment of claim 1, from which claim 11 depends fails to obviate the rejection of claim 11, because claim 11 is drawn to a

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composition comprising an indocyanine green derivative that is derived from indocyanine green-N-hydroxysuccinimide ester.

6. The rejection of claim 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons of record. The amendment of claim 1, from which claim 11 depends fails to obviate the rejection of claim 11, because claim 11 is drawn to a composition comprising an indocyanine green derivative that is derived from indocyanine green-N-hydroxysuccinimide ester.

7. Claims 14-21, 23-25, and 30-36 is/remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record. The rejection of claims 27-29 is withdrawn in view of the amendment changing the dependency of claim 27. The rejection of claims 30-32 is added in view of the amendment changing the dependency of claim 30. The rejection is maintained because the specification, while being enabling for methods comprising contacting the tumor cell or the malignant neoplasia of epithelial cells with an antibody that is specific for a tumor cell or a malignant neoplasia of epithelial cells, does not reasonably provide enablement for methods comprising contacting the tumor cell or the malignant neoplasia of epithelial cells with any antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments have been carefully considered but fail to persuade. Applicants' arguments appear to be directed to the question of the enablement of the composition claims,

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which were not rejected. The reason the method claims are rejected is that the method claims are all directed to methods staining tumor cells, or diagnosis of malignant neoplasia of epithelial cells. The specification does not make clear how one of skill in the art may use composition for these purposes, where the composition comprises any antibody. For these methods to be useful one of skill in the art must use an anti-cancer antibody. Therefore, the rejection is maintained for the reasons of record.

New Grounds of Rejection:

8. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 depends from claim 1, which sets forth a limited set of indocyanine green derivative, whereas claim 11 is drawn to a composition comprising an indocyanine green derivative that is "derived" from indocyanine green-N-hydroxysulfosuccinimide ester. Because the phrase "derived from" is interpreted to mean that the derivative may be compound that has only one molecule in common with indocyanine green-N-hydroxysulfosuccinimide, the scope of claim 11 is broader than the scope of claim 1.

Conclusion

Claims 11, 14-21, 23-25 and 30-36 are rejected. Claims 1-7, 12, and 26-29 are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
February 22, 2005


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER